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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/227,854 01/11/99 NI

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022195 HM22/0615
HUMAN GENOME SCIENCES INC
9410 KEY WEST AVENUE
ROCKVILLE MD 20850

EXAMINER

PRASAD, S

ART UNIT

PAPER NUMBER

1646

DATE MAILED:

06/15/01

Pl ase find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.

09/227,854

Applicant(s)

Ni et al.

Examiner

Sarada C Prasad

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 and 25-59 is/are pending in the application.
- 4a) Of the above claim(s) 1-19,25-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

Detailed Action

1. Receipt of Applicants' arguments and amendments filed in Paper No. 9 (4/2/01) is acknowledged in response to an earlier office action (Paper No. 7, 11/2/00) directed to claims 35-59. Pending claims 35-59 are under consideration by the Examiner in the current office action.
2. The following previous rejections and objections are withdrawn in light of Applicants' amendments filed in Paper No. 9 (4/2/01).
 - (i) the rejection of claims 38, 55 under 35 U.S.C. 112, second paragraph for reasons of the dependent claim being broader in scope;
 - (ii) the rejection of claims 45-46 under 35 U.S.C. 112, second paragraph, as being duplicates of claims 37-38;
 - (iii) rejection of claims 44 and 54 under 35 U.S.C. 112, first paragraph based on lack of a recovery step or purification critical or essential to the practice of the invention.
3. Applicant's arguments filed in paper No. 9, 4/2/01 have been fully considered but were deemed persuasive in part. The issues remaining and new issues, are stated below.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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5. Claims 35-59 are rejected under 35 USC § 101 because they are drawn to an invention with no apparent or disclosed utility.

The instant application has provided a description of a chemotactic cytokine I derived from human adult liver cDNA, methods of making and its possible biological activities. The breadth of its biological functions and possible uses have been disclosed in the specification, and they are largely dependent upon the structural homology of the instant cytokine to human MRP-14 (46.739%) and to S100 protein (56% identity) (in particular, see page 7, 4th para, lines 4-9). The instant invention lacks patentable utility because the phenomena of the ligand, the instant cytokine I, binding to its receptor and transduction of the signal for the claimed effectiveness and functionality of the chemotactic cytokine are hypothetical. It is clear from the instant specification that the cytokine I of SEQ ID No. 2 retains calcium binding motifs present in all S100 members. There is little doubt that, after further characterization, this protein will probably be found to have a patentable utility. This further characterization, however, is part of the act of invention and until it has been undertaken Applicant's claim of therapeutic utility as a novel cytokine is incomplete.

The instant situation is analogous to that which was addressed in *Brenner v Manson*, 148 USPQ 689 (SUS. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which are known to possess anticancer activity was alleged to be a potential antitumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 USC 101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The court held that:

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"The basic quid pro contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-here is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and a "patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion".

The instant claims are drawn to polypeptides which exhibit 40-70% homology to calcium binding proteins and S100 proteins, however, as of yet not shown to have their own identity by way of demonstrated biological effects or functions. Until some actual and specific significance can be attributed to the proteins identified in the specification as SEQ ID NO. 2, the instant invention is incomplete. In the absence of knowledge of the biological significance of these proteins, there are no immediately obvious patentable uses for these S100-like homologues. Since the instant invention does not disclose a "real world" use for proteins of SEQ ID NO. 2, the claimed invention is incomplete, and therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

Claims 35-59 are also rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial utility or well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112-enablement

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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6. Claims 35-59 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

X The written description in this case sets forth the amino acid sequence for human chemotactic cytokine I polypeptide of SEQ ID No: 2 and no distinction was drawn between mature and secreted forms or preprocessed forms. Therefore, the written description is not commensurate in scope with the claims drawn to mature forms of the polypeptide of SEQ ID NO: 2.

Vas-Cath Inc. Mahurkar, 19 USPQ2d 1111, clearly states that ‘applicant must clearly convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is for purposes of the ‘written description’ inquiry, ‘whatever is now claimed’ (see page 1117). The specification does not ‘clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed’ 9see *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 1115).

The Applicants claim mature form of the polypeptide of SEQ ID NO: 2 encoded by the human cDNA contained in the ATCC Deposit No. 97304. However, mature forms, and secreted forms of this polypeptide have not been disclosed in the instant specification. Furthermore, beyond the mere mention of mature forms and secreted forms and general methods of how to isolate such forms (pages 8-10 of specification), no disclosure is made in the specification of the

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mature forms of human chemotactic chemokine polypeptides. This is insufficient to support the generic claims as provided by the Revised Written description Guidelines published in the Federal register, vol 66, No.4, pages 1099-1111, Friday January 2001.

Claim Rejections - 35 USC § 102

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

7. Claims 35-59 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,976,832 (Hitomi J et al.) The claims of the instant invention are drawn to an isolated polypeptide comprising at least 30 contiguous amino acid residues of SEQ ID NO:2, including residues 1-92. The claims are drawn to isolated polypeptides encoded by the human cDNA contained in the ATCC Deposit No. 97304 and methods of making them.

Hitomi et al. (U.S. Patent No. 5,976,832) teach an isolated polynucleotide comprising residues 1-92 of SEQ ID NO: 2 (see the sequence comparison provided). Hitomi et al. also teach vectors comprising the polynucleotides, host cells and processes for producing the protein encoded for by the polynucleotides of the invention (column 5, line 4). The DNA and the protein of Hitomi et al. correspond to SEQ ID NO:1 and 2 of the instant application, respectively, thereby anticipating claims 35-59. It should be noted, however, that amino acid residue 15 of SEQ ID NO: 2 of Hitomi et al. should be Phe, but it is incorrectly labeled Ile.

8. Conclusion

No claims are allowed.

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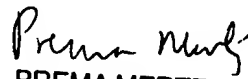
Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarada C Prasad whose telephone number is 703-305-1009. The examiner can normally be reached Monday - Friday from 8.00 AM to 4.30 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Sarada Prasad, Ph.D.
Examiner Art Unit 1646
June 10th, 2001


PREMA MERTZ
PRIMARY EXAMINER

ALIGNMENTS

RESULT 1
 US-08-568-310D-20
 ; Sequence 20, Application US/08568310D
 ; Patent No. 5976832
 ; GENERAL INFORMATION:
 ; APPLICANT: HITOMI, JIRO
 ; APPLICANT: YAMAGUCHI, KEN
 ; APPLICANT: YAMAMURA, TOKUJIRO
 ; APPLICANT: KIMURA, TATSUJI
 ; TITLE OF INVENTION: NOVEL CALCIUM-BINDING PROTEINS
 ; NUMBER OF SEQUENCES: 20
 ; CORRESPONDENCE ADDRESS:
 ; ADDRESSEE: WYATT, GERBER, MELLER & O'ROURKE
 ; STREET: 99 PARK AVENUE
 ; STREET: 6th FLOOR
 ; CITY: NEW YORK CITY
 ; STATE: NEW YORK
 ; COUNTRY: USA
 ; ZIP: 10016
 ; COMPUTER READABLE FORM:
 ; MEDIUM TYPE: DISKETTE, 3.50 INCH, 720 Kb
 ; MEDIUM TYPE: STORAGE
 ; COMPUTER: IBM-PC COMPATIBLE
 ; OPERATING SYSTEM: PC-DOS 6.2
 ; SOFTWARE: WORDPERFECT 6.1
 ; CURRENT APPLICATION DATA:
 ; APPLICATION NUMBER: US/08/568,310D
 ; FILING DATE: DECEMBER 6, 1995
 ; CLASSIFICATION: 435
 ; PRIOR APPLICATION DATA:
 ; APPLICATION NUMBER: 7-70468 and 7-45564(both Japan)
 ; FILING DATE: 3/6/95 and 3/6/95, respectively
 ; ATTORNEY/AGENT INFORMATION:
 ; NAME: KLEIN, MILTON
 ; REGISTRATION NUMBER: 27101
 ; REFERENCE/DOCKET NUMBER: 3316
 ; TELECOMMUNICATION INFORMATION:
 ; TELEPHONE: (212)953-3350
 ; TELEFAX: (212)953-3352
 ; INFORMATION FOR SEQ ID NO: 20:
 ; SEQUENCE CHARACTERISTICS:
 ; LENGTH: 92
 ; TYPE: amino acid
 ; STRANDEDNESS:
 ; TOPOLOGY: linear
 ; MOLECULE TYPE: cDNA
 ; PUBLICATION INFORMATION:
 ; RELEVANT RESIDUES IN SEQ ID NO: 20:
 ; RELEVANT RESIDUES IN SEQ ID NO: FROM 1 TO 92
 US-08-568-310D-20

Query Match 100.0%; Score 468; DB 2; Length 92;
 Best Local Similarity 100.0%; Pred. No. 3e-49;
 Matches 92; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

QY 1 MTKLEEHLEGIVNIFHQYSVRKGHFDTLKSGELKQLLTKELANTIKNIKDKAVIDEIFQG 60
 Db 1 MTKLEEHLEGIVNIFHQYSVRKGHFDTLKSGELKQLLTKELANTIKNIKDKAVIDEIFQG 60
 QY 61 LDANQDEQVDFQEFISLVAIALKAAHYHTHKE 92
 Db 61 LDANQDEQVDFQEFISLVAIALKAAHYHTHKE 92